Oscar Clinical Guideline: Entecavir (Baraclude) (PG085, Ver. 6)

# Entecavir (Baraclude)

**Disclaimer**

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

## Summary

Chronic hepatitis B is a viral infection of the liver caused by the hepatitis B virus (HBV). It can lead to cirrhosis, liver failure, and hepatocellular carcinoma if left untreated. The goal of treatment is to suppress viral replication, reduce liver inflammation, and prevent disease progression.

Treatment options for chronic hepatitis B include nucleos(t)ide analogues (NAs) and interferon-based therapies. NAs, such as entecavir, tenofovir alafenamide, and tenofovir disoproxil fumarate, are the mainstay of treatment due to their high efficacy and favorable safety profile. Entecavir (Baraclude) is a potent NA that inhibits HBV replication. It is available as tablets and oral solution, and is indicated for the treatment of chronic HBV infection in adults and children 2 years of age and older with evidence of active viral replication and either persistently elevated serum aminotransferases or histologically active disease.

## Definitions

"**ALT** and **AST**" refer to alanine aminotransferase and aspartate aminotransferase, liver enzymes that indicate liver cell injury when elevated.

"**HBeAg**" refers to hepatitis B e antigen, a marker of HBV replication.

"**HBsAg**" refers to hepatitis B surface antigen, indicating current HBV infection.

"**Anti-HBc**" refers to antibody to hepatitis B core antigen, indicating current or past HBV infection.

"**HBV DNA**" refers to hepatitis B virus DNA, a measure of viral load and replication.

"**Decompensated Liver Disease**" is a severe stage of chronic liver disease characterized by the presence of complications such as variceal bleeding, ascites, hepatic encephalopathy, or abnormal liver function tests. It indicates a failure of the liver to perform its normal metabolic and synthetic functions.

"**Nucleos(t)ide analogue**" refers to a class of antiviral medications that inhibit HBV replication by interfering with viral DNA synthesis.

## Medical Necessity Criteria for Initial Authorization

The Plan considers **entecavir (Baraclude)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

### Treatment of chronic hepatitis B virus infection

1. The requested medication is being prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist***; AND***
2. The member is 2 years of age or older***; AND***
3. The member has a documented diagnosis of chronic hepatitis B virus (HBV) infection, confirmed by appropriate laboratory test***; AND***
4. If the member is coinfected with human immunodeficiency virus (HIV) or chronic hepatitis C virus (HCV), the member meets **ONE** (1) of the following:
    a. the member has hepatitis B and HIV coinfection AND is receiving a fully suppressive antiretroviral (ARV) treatment regimen for HIV; ***or***
    b. the member is coinfected with hepatitis B and chronic HCV and is currently receiving hepatitis C direct-acting antiviral (DAA) therapy***; AND***

5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Hepatitis B virus reactivation prophylaxis

1. The requested medication is being prescribed by or in consultation with an oncologist, gastroenterologist, hepatologist, infectious disease, or transplant specialist***; AND***
2. The member is 2 years of age or older***; AND***
3. The requested medication is being used for prophylaxis against hepatitis B reactivation **AND** the member meets **ONE** of the following:
    a. is anti-HBc-positive, HBsAg-positive **AND** receiving immunosuppressive or cytotoxic (e.g., anticancer) therapy; ***or***
    b. is anti-HBc-positive, HBsAg-negative **AND** undergoing stem cell transplantation or receiving anti-CD20 therapy, such as rituximab; ***or***
    c. is a non-liver solid organ transplant recipient of **ONE** (1) of the following:
        i. a HBsAg-positive extrahepatic organ; ***or***
        ii. an anti-HBc-positive, HBsAg-negative organ***; AND***
4. If the member is coinfected with human immunodeficiency virus (HIV) or chronic hepatitis C virus (HCV), the member meets **ONE** (1) of the following:
    a. the member has hepatitis B and HIV coinfection AND is receiving a fully suppressive antiretroviral (ARV) treatment regimen for HIV; ***or***
    b. the member is coinfected with hepatitis B and chronic HCV and is currently receiving hepatitis C direct-acting antiviral (DAA) therapy***; AND***
5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Hepatitis B virus reinfection prophylaxis

1. The requested medication is being prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease, or transplant specialist***; AND***
2. The member is 2 years of age or older***; AND***
3. The requested medication is being used for prophylaxis of hepatitis B virus (HBV) reinfection **AND** the member has a documented history of **BOTH** of the following:
    a. chronic Hepatitis B infection***; and***
    b. has undergone a liver transplant***; AND***
4. If the member is coinfected with human immunodeficiency virus (HIV) or chronic hepatitis C virus (HCV), the member meets **ONE** (1) of the following:

a. the member has hepatitis B and HIV coinfection AND is receiving a fully suppressive antiretroviral (ARV) treatment regimen for HIV; ***or***
b. the member is coinfected with hepatitis B and chronic HCV and is currently receiving hepatitis C direct-acting antiviral (DAA) therapy***; AND***

5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

### Additional criterion for oral solution (i.e., Baraclude 0.05mg/mL Solution)

6. For requests for **entecavir oral solution**, the member meets **ONE** of the following:
    a. The member is unable to swallow tablets***; OR***
    b. The member requires a dose that cannot be achieved with commercially available tablet strengths***; OR***
    c. The prescriber provides a clinically valid reason why the oral solution is necessary instead of the tablet formulation.

**If the above prior authorization criteria are met, entecavir (Baraclude) will be approved for 12 months.**

### Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following criteria are met:

1. The member continues to meet all initial authorization criteria; ***AND***
2. Recent (within the last 3 months) chart and laboratory test results documentation shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** (1) of the following:
    1. a decrease or suppression of serum HBV DNA levels (viral load, reported in international units/mL or in copies/mL) compared to baseline (pre-treatment); ***or***
    2. a decrease or normalization of serum aminotransferase (ALT or AST) concentrations compared to baseline (pre-treatment); ***or***
    3. undetectable levels of serum HBV DNA or only minimal histologic evidence of liver injury.

## Experimental or Investigational / Not Medically Necessary

Entecavir (Baraclude) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

## References


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## Clinical Guideline Revision / History Information

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